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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,101	08/27/2001	Mary E. Gerritsen	GENENT.072A2	4279

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/940,101

Applicant(s)

GERRITSEN ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Restriction/Election Fax*.

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## DETAILED ACTION

*Claims 1-84 are pending.*

### ***Restriction Requirement***

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax numbers are (703-872-9306 (before final) and 703-872-9307 (after final)). A Fax cover sheet is attached to this Office Action for your convenience.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 – 21, drawn to a method of controlling excessive proliferation, comprising treating smooth muscle cells with antagonist of native ErbB4 receptor, wherein antagonist is immunoadhesin, classified in Class 424, subclass 193.1.

II. Claims 1-14 and 22 – 27, drawn to a method of controlling excessive proliferation, comprising treating smooth muscle cells with antagonist of native ErbB4 receptor, wherein antagonist is antibody, classified in Class 424, subclass 130.1.

III. Claims 28-35 and 40-45 drawn to a method for treating stenosis in a mammalian patient comprising administering to said patient an effective amount of an antagonist, wherein antagonist is immunoadhesin, classified in Class 424, subclass 193.1.

IV. Claims 28-31, 36-45 drawn to a method for treating stenosis in a mammalian patient comprising administering to said patient an effective amount of an antagonist, wherein antagonist is antibody, classified in Class 424, subclass 130.1.

V. Claims 46-49 and 55-56 drawn to a method for treating stenosis in a mammalian patient comprising introducing into a cell of said patient a nucleic acid encoding an antagonist of an ErbB4 receptor wherein antagonist is immunoadhesin, classified in Class 514, subclass 44.

VI. Claims 46-47 and 50-56 drawn to a method for treating stenosis in a mammalian patient comprising introducing into a cell of said patient a nucleic acid encoding an antagonist of an ErbB4 receptor wherein antagonist is antibody, classified in Class 514, subclass 44.

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VII. Claims 57 and 58 drawn to a method for treating hypertension, classified in Class 424, subclass 193.1.

VIII. Claim 59 drawn to a pharmaceutical composition for the treatment of stenosis, comprising antagonist of native mammalian ErbB4 receptor, wherein antagonist is immunoadhesin, classified in Class 424, subclass 193.1.

IX. Claims 59, 66-77 and 81-84 drawn to a pharmaceutical composition for the treatment of stenosis, comprising antagonist of native mammalian ErbB4 receptor wherein antagonist is antibody, classified in Class 424, subclass 130.1.

X. Claims 60 -63 drawn to a method for identifying a molecule that inhibits the proliferation of smooth muscle cells, classified in Class 424, subclass 193.1.

XI. Claims 60 -65 drawn to a method for identifying a molecule, wherein said molecule is antibody, that enhances the proliferation of smooth muscle cells, classified in Class 424, subclass 130.1.

XII. Claims 60 -65 drawn to a method for identifying a molecule, wherein said molecule is small molecule, that enhances the proliferation of smooth muscle cells, classified in Class 424, subclass 193.1.

XIII. Claims 78-80 drawn to an antibody which binds both ErbB4 and ErbB3, classified Class 424, subclass 130.1.

3. Groups I -VII and X-XII are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups VIII, IX and XIII are different products. Pharmaceutical composition for the treatment of stenosis, comprising antagonist, wherein antagonist is immunoadhesin or antibody which binds both ErbB4 and ErbB3 differ with respect to their structures, physicochemical properties and mode of action; therefore each product is patentably distinct.

5. Groups VIII /I, III and IX /II, IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the antibody of Group IX can be used for affinity purification and immunoadhesin of group VIII can be used as an antigen for production of antibody, in addition to the methods of controlling excessive proliferation and treating stenosis.

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6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Group I is elected, applicant is required to elect a specific method of controlling excessive proliferation, comprising treating smooth muscle cells with antagonist of native ErbB4 receptor, wherein specific immunoglobulin is selected from the group recited in Claim 20.

These species are distinct because a specific method of controlling excessive proliferation, comprising treating smooth muscle cells with antagonist of native ErbB4 receptor, wherein specific immunoglobulin is selected from the group recited in Claim 20 differ with respect to the specific antagonist; thus each specific method employing a specific antagonist represents patentably distinct subject matter. Furthermore, the examination of specific immunoglobulin selected from the group recited in Claim 20 in the methods of controlling excessive proliferation would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 5, 2002

  
**CHRISTINA CHAN**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**